

Basis for Amendments and Claim to Benefit of an Earlier Filing Date

Applicants have amended Claims 29 and 30, the only claims pending and not withdrawn, to refer to the amino acid sequence of SEQ ID NO: 21. Sequence 21 is newly introduced by amendment herein, together with the appropriate sequence listing. It does not, however, introduce new matter. Sequence 21 is the exact 380 amino acid sequence that appeared in U.S. Patent Application Serial No. 08/585,758 which was filed January 16, 1996. The same disclosure is incorporated into the Specification by reference as originally filed on October 29, 2003. See, page 1, lines 1-4. This same 380 amino acid sequence has literally been present, as incorporated by reference, in each of U.S. Patent Application Serial Nos. 09/804,690, 09/146,187, 08/977,818 and 08/670,274, the priority of each of which is claimed herein. It is also present in U.S. Patent Application Serial No. 60/006,856, but given that the January 16, 1996 filing date comes in advance of all cited prior art, treatment of the claim to benefit of the provisional herein is moot.

It is unclear from the Examiner's consideration of the issue of Priority at pages 2-3 of the outstanding Office Action whether he is aware of the incorporation by reference of this sequence or not. The Office Action indicates that "the prior applications set forth and/or describe an amino acid sequence that consists of the amino acid sequence spanning positions 11 to 390 of SEQ ID NO: 4, but none describe the entirety of SEQ ID NO: 4 and none describe the claimed genus of polypeptides comprising the particular fragment of SEQ ID NO: 4 spanning positions 11-390; and accordingly none describe the claimed subject matter." The logic is unclear. The Examiner concedes that the exact sequence recited in the claims, beginning with a Met at residue 1, continuing through to an Arg at position 40, a Gly at position 90, a Leu at position 220, a Glu at position 235, an Asp at position 305 and on through Tyr at position 380, isolated and identified, and each of the residues in between, appears in each of the priority applications. It appears in this application. Applicants are not claiming SEQ ID NO: 4, or any aspect thereof. Applicants are claiming a sequence of amino acids clearly and specifically identified in each of the cases in the priority chain. The fact that it was identified as SEQ ID NO: 4 in the original priority case, and is SEQ ID NO: 21 herein, as introduced in this amendment, surely does not change its identity or the clear description of the same. Applicants are entitled to the benefit of the filing date of no later than January 16, 1995.

Acknowledgement of the same in the next action is respectfully requested.

Written Description

The Specification is objected to, and the Claims rejected, as lacking written description of the 380 amino acid sequence now recited as SEQ ID NO: 21. At page 5 of the Office Action, the Examiner notes "Applicant is advised that the issue cannot be remedied by amended the disclosure to include antecedent basis for the language of the claims without introducing new matter into the disclosure." Respectfully, Applicants disagree.

The Examiner concedes that each of the priority applications from which benefit is claimed "set forth in their Sequence Listings and/or describe an amino acid sequence consisting of the sequence spanning the amino acids positions 11-390 of SEQ ID NO: 4". Office Action, page 7.

As noted above, by virtue of the incorporation by reference of the exact language of U.S. Patent Application Serial No. 08/585,758, that exact 380 amino acid sequence, now fully set forth as SEQ ID NO: 21, appears in the Specification of this application as filed back in 2003 as well. It doesn't matter which sequence number it appears as, this exact 380 amino acid sequence, as well as the 390 amino acid sequence of SEQ ID NO: 4, literally appear in the application. Applicants attempted to point this out by reciting the exact sequence in Claim 29 in the Amendment of October 5, 2009. The previous Examiner refused to enter that amendment because "it is not associated with a SEQ ID number." Advisory Action of October 28, 2009, page 2. While this does not appear to be a basis for not entering an amendment, as opposed to objecting to the disclosure, see, MPEP 2421.02, Applicants acquiesced, in hopes of accelerating the 7 year prosecution of this application by appealing the rejection of claims that refer to SEQ ID NO: 4.

In an effort to moot this issue, the 380 amino acid sequence that has been present in the disclosure of this application and each of its §120 parent applications since 1995 is now given a sequence separate from the 390 amino acid sequence of the mature TSG101 protein. Withdrawal of the objection to the Specification and rejection of the claims for lacking a written description of the subject matter of the claims presented is respectfully requested.

Applicants appreciate the suggestion of Examiner Rawlings that the amendment to the Specification to change SEQ ID NO: 4 to the full mature protein "may have been in error" and suggesting a replacement sequence listing that replaces the 390 amino acid sequence with the 380 amino acid sequence claimed. Respectfully, while Applicants have embraced the suggestion of introducing a replacement sequence listing to include sequence 21, the exact sequence claimed, the introduction of the 390 amino acid sequence was not an error. TSG101

in its mature form is in fact a 390 amino acid protein as recited in Sequence 4. However, as noted in the Specification at page 14, line 14 – page 15, line 20, polypeptides comprising some but not all of that sequence also have value. The sequence of the claims, Sequence 21, recites one such polypeptide. Acceptance is respectfully requested, and withdrawal of the rejections for lack of written description respectfully requested.

Claim Rejections – 35 U.S.C. § 102

The rejection of Claims 29 and 30 under 35 U.S.C. 102(b), as being anticipated by the disclosure by GENBANK Accession No. U82130.1 (04 June 1998)(of record), is maintained.

Claims 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by the disclosure by Li et al. (*Cell*. 1997 Jan 10; 88: 143-154).

Claims 29 and 30 are rejected under 35 U.S.C. 102(b) as being anticipated by the disclosure by U.S. Patent No. 6,586,185.

As the claims, upon introduction of the above amendment and acceptance of the replacement sequence listing are entitled to benefit of priority back to at least 1996, the references relied upon are not prior art, and the rejections are respectfully traversed.

The Course of Prosecution

Since the Office Action of August 31, 2006, more than four years ago, the issue contested in this application was joined, and has never changed. The sole issue is whether Applicants are entitled to the benefit of the parent applications claimed. In their response of February 27, 2007 applicants took pains to note that in fact, the disclosure of the polypeptide of 380 amino acids which is at the core of Applicants' claims has been present in each case filed in the chain, including the current application, by reason of incorporation of reference. Page 4.

Four years later we are mired in prosecution over the exact same issue. It is not wrong for Applicants and the Office to have a different position over the claims – that is why there is an appeal process. What is wrong is to extend prosecution, and delay in protection, for four years while the same issue is batted back and forth. Applicants have twice filed Appeal Briefs in this case, and twice had the application withdrawn from appeal to issue new rejections over the same references based on the same argument. At page 8 of the outstanding Office Action, the Examiner references "recent interviews."

Respectfully, the disclosure of this application includes polypeptides which are 390 amino acids in length (SEQ ID NO: 4) and 380 amino acids in length (SEQ ID NO: 21). Inclusion

of both is important. For purposes of benefit of priority, only the presence of that which is claimed, polypeptides comprising the 380 amino acid sequence of SEQ ID NO: 21 is of importance. That sequence is present in the priority cases. It is referred to in the priority cases as SEQ ID NO: 4. If it is the Examiner's position that identifying the same sequence with different numbers is a bar to priority under 35 U.S.C. §120, then the case should proceed to appeal on an expedited basis. If the Examiner agrees that the claims presented are entitled to priority, but objects to the language included, then the Examiner is respectfully requested to contact Applicants' representative to hasten prosecution.

Reconsideration of Restriction is Requested

The claims in this case continue to include two claims drawn to a polypeptide and withdrawn claims drawn to the antibody of the polypeptide and the complex of the polypeptide and the antibody. Given the second withdrawal of this case from Appeal, reconsideration of the refusal of the Examiner to examine withdrawn Claims 31–34 is requested.

The sole basis advanced for the restriction is that searching all six claims would impose an unreasonable burden. This is not clearly understood. It has been the law in this country for some time that given a polypeptide of significant length, the antibody thereto is presumed obvious. While the presumption can be overcome, Applicants do not so argue herein, and concede that if in fact the polypeptide of Claims 29 and 30 is old in the art, then the withdrawn Claims 30–34 would be anticipated or obvious over that same art. There can be no unreasonable burden under these circumstances – the search is identical. Withdrawal of the restriction requirement is respectfully requested.

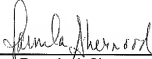
Conclusion

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-0815, order number STAN-010CON2.

Respectfully submitted,
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